REMARKS/ARGUMENTS

Claim 10 is cancelled. Applicant submits that the cancellation of this claim renders moot all rejections of it.

New claim 11 limits the solid tumors to those specified on page 2 of the specification and limits the epothilone derivative to epothilone B. Applicant requests entry of this new claim because the Examiner indicated that a claim with such limitations would overcome the rejection under 35 USC 112, first paragraph.

Claims 1-5 were rejected as not meeting the enablement requirement of 35 USC 112, first paragraph. Applicants request reconsideration of this rejection for the reasons that follow.

Although this is an enablement rejection, the Examiner does not assert that one of skill would not know how treat solid tumors with the combination partners utilized according to the present claims. Instead, the Examiner contends that: "...generically treating solid tumors is broad and one cannot reasonably use a single drug to treat a vast variety of solid tumors ..." Thus, it is clear that the present rejection is not made because undue experimentation would be required to carry out the invention, but because the Examiner doubts the objective teaching of this application that the present combination would provide a benefit for the treatment of solid tumors generally.

However it is the Examiner's burden to explain why they doubt the truth or accuracy of statements in the disclosure and to back up assertions with acceptable evidence or reasoning. See, In re Marzocci, 169 USPQ 367, 369-370 (CCPA 1971). In this instance, the Examiner merely states that solid tumor disease is a broad genus. Applicant asserts that the Examiner's burden is not met by such a conclusory statement. Since the Examiner has not provided any objective evidence to doubt the teaching of the present specification that the present combination would provide a benefit for the treatment of solid tumors, the rejection under the enablement requirement of 35 USC 112, first paragraph, is improper. Accordingly, Applicant requests withdrawal of this rejection.

Applicant further notes that new claim 11 limits the solid tumors to those specified on page 2 of the specification as suggested by the Examiner. Applicant appreciates the Examiner's helpful suggestion.

Claims 1-5 were rejected under 35 USC 102(e) as anticipated by Vite et al. Applicants request reconsideration of this rejection for the reasons that follow.

In response to the Examiner: The Examiner points to no example or disclosure in Vite et al where any compound within the scope of the reference's formula V is used in combination with radiation to treat a solid tumor disease. The Examiner is correct that Vite et al discloses epothilones A and B at column 1, lines 15-30. However, it discloses that these compounds are in the state of the art with respect to the compounds that the reference is concerned with. Applicant further directs the Examiner's attention to Vite et al, column 2, lines 45-54, where the reference excludes epothilones A and B from the scope of the invention. The Examiner refers to Example 7. However, in Vite et al's Example 7, the thiazole ring is substituted by hydroxymethyl. In contrast, the thiazole ring of the present epothilone compounds is specifically defined to be methyl, and is never hydroxymethyl. Thus, the compound described in Example 7 is distinguished from the compounds within the scope of the present claims.

The present claims are directed the treatment of solid tumors with a small genus of compounds in combination with ionizing radiation. The Examiner points to no example or other disclosure in Vite et al where the reference actually uses a compound within the scope of the present claims in combination with radiation to treat a solid tumor disease. Therefore, the reference does not disclose a species within scope of the present claims. See, MPEP 2131.02.

It is clear that the present invention is not specifically disclosed in Vite et al and that the Examiner is piecing together portions of its generic disclosure to make the anticipation rejection. MPEP 2131.02, discusses In re Petering, 133 USPQ 275 (CCPA 1963), as an instance where a generic disclosure anticipated a compound that was not specifically disclosed in a reference. In that case, the reference taught a pattern of preferences that lead one of ordinary skill to at once envisage a limited group of 20 compounds such that each of the permutations was anticipated. That is not the situation here.

The Examiner has cited no pattern of preferences or other disclosure in Vite et al that would lead the skilled artisan to choose: (1) the present compounds from the myriad of possibilities, (2) to choose to use the present compounds to treat solid tumors from all of the possible uses disclosed in the reference and (3) to combine the present compounds with ionizing radiation, rather than use them alone or with one of the many other potential combination partners disclosed in the reference. Indeed, there appears to be no disclosure in Vite et al of which compounds would be preferred for the treatment of solid tumors or which compounds might be preferred for combination therapy with ionizing radiation. The only preference taught by the reference appears to be at the paragraph bridging columns 6 and 7,

where it teaches to use compounds that are clearly not within the scope of present claims 2, 3 or new claim 11. However, even this preference is just a general indication of which compounds are preferred and does not teach a preference to use even the preferred compounds with radiation or for the treatment of solid tumors. It is clear that the present situation is not analogous to Petering and that such a disclosure does not anticipate the present invention under the law set forth in Petering.

The present situation is much more analogous to that decided in Warner-Jenkinson v. Allied Chemical Corp., 206 USPQ 837, 848 (S.D.N.Y. 1979). This case involved the patentability of Red Dye #40. The court held that Red Dye #40 was not anticipated by a reference that did not describe Red Dye #40 by specific words or structure even though one could arrive at the structure of Red Dye #40 by picking and choosing from the reference's generic disclosure. In order to arrive at Red Dye #40, one would have had to choose one from twenty seven generic formulae and then choose from among over one hundred separate isomers.

Analogously to the Warner-Jenkinson case, in the present instance, one would have to pick and choose from three large generic disclosures of Vite et al: (1) Vite et al's formula V embraces a large genus, which includes thousands, if not millions, of compounds. (2) The reference generally discloses that any and all of this panopoly of compounds can be used to treat any of the conditions described from column 5, line 23, to column 6, line 17. (3) The reference provides further general disclosure that when treating any of these conditions, the compounds of formula V could be combined with, not only radiation, but any of the therapeutic agents disclosed from column 6, lines 18-41, many of which are described by therapeutic class and thus themselves describe large genus of therapeutic agents. Clearly, such a disclosure does not identically disclose any of the combinations one could arrive at by picking and choosing from the reference's generic disclosure.

Therefore, the claims are not anticipated by Vite et al and Applicant requests withdrawal of the rejection under 35 USC 102(b) or 35 USC 102(e) over Vite et al.

Applicant further asserts that the present claims are not *prima facie* obvious over the broad generic disclosure of Vite et al. In addition, the Examiner's attention is directed the experiments described in Hofstetter et al and Bley et al, which were submitted previously. Applicant further notes that claim 3 and new claim 11 are limited to the epothilone derivative used in these experiments.

Entry of this response and reconsideration and allowance of the claims are requested.

Respectfully submitted,

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